REMARKS

The amendment to claim 2 does not add new matter. In particular, claim 2 has been amended to clarify the language and recite that "said graft is obtained from porcine, bovine, equine, goat ~~and~~ or other ruminant ~~sources~~ source." Applicants request that the Examiner exercise his discretion under 37 C.F.R. § 1.116 and enter this amendment because it does not require any additional consideration by the Patent Office and merely places the claim in better condition for appeal.

For all these reasons, the amendment to claim 2 is fully supported by claim 2 as originally filed and does not add new matter.

Summary of the Bases for Rejection

Claims 1, 2, 4, 8, 9, and 31-40 3, 7-11 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat 5,067,962 ("Campbell") in view U.S. Patent No. 5,961,520 ("Beck").

I. 35 U.S.C. §103(a) Campbell in view of Beck

Claims 1, 2, 4, 8, 9, and 31-40 3, 7-11 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat 5,067,962 ("Campbell") in view U.S. Patent No. 5,961,520 ("Beck"). According to the Patent Office, Campbell discloses a "xenograft replacement ligament comprising a bone-ligament-bone attachment with a naturally occurring [ligament to bone] attachment (see abstract and Fig. 3)" and that "Figure 3 discloses bone blocks shaped into a dowel." [Official Action at page 2.] The Patent Office admits, "Campbell et al does not disclose a groove along the length of each bone block." [Official Action at page 2.]

To make up for the admitted deficiency in Campbell, the Patent Office cites to Beck. According to the Patent Office, Beck "discloses an artificial ligament comprising an anchoring system made of bone (see col. 6, lines 36-39) and having a groove along the length (see Fig. 2, see element 17) for the purpose of inserting an attachment screw and attach the attachment system to the patient's bone." [Official Action at page 2.] The Patent Office then concludes that "[i]t would have been obvious to one of ordinary skill in

the art at the time the invention was made to modify the bone blocks of the Campbell et al reference with **the longitudinal groove (see surface 17) of the Beck, Jr. et al. reference**, in order to insert an attachment screw and attach the attachment system to the patient's bone." [Official Action at pages 2-3 (bridging sentence).] The Applicants respectfully disagree.

A. The Addition of the groove of Beck to the graft of Campbell fails to provide a graft that would be useful in orthopedic surgery

The addition of **the longitudinal groove of the Beck, Jr. et al reference** to the shaped xenograft bone-ligament-bone (aka Bone-Tendon-Bone) graft of Campbell would not provide a xenograft bone-tendon- bone graft that would be **useful in orthopedic surgery**. Claim 1 of the Applicants invention is directed to "A xenogenic bone-tendon-bone graft **useful in orthopedic surgery**. . ." Specifically, the bone block ends of the bone-ligament-bone graft of Fig. 3 of Campbell (which is relied upon by the Patent Office) are not dowels as alleged. They are frustoconical in shape wherein the ends of each bone block that are furthest from the ligament have a smaller diameter (and circumference) than the ends of the bone block that are attached to the ligament. By way of analogy, the bone blocks of the xenogeneic bone-ligament-bone graft of Campbell are shaped like tapered bottle corks that fit into the appropriately tapered hole. This is shown in Fig. 4 of Campbell. In order to retain the tapered bone blocks in their correspondingly shaped tapered holes, Campbell discloses the use of holes 25 and 26 in the tapered blocks of Figure 3, which receive a stainless steel pins 30 and 32 to anchor the corresponding bone blocks to the femur and the tibia:

> Installation of the replacement ligament 11 as an anterior cruciate ligament between a femur 27 and a tibia 28 results in the replacement ligament installation 10 illustrated in **FIG. 4**. The bone plug 23 is implanted or placed within a first recess 29 formed by suitable known means in the femur 27 at the naturally occurring attachment site on the femur 27 of the ligament being replaced. There, it is attached or anchored to the femur 27 by suitable means such as a **first stainless steel pin 30 through the hole 25**. Similarly, the bone plug 24 is placed within a second recess 31 formed in the tibia 28 at the naturally occurring attachment site on the tibia 28. There, it is attached or anchored to the tibia 28 by

> suitable means such as a **second stainless steel pin 32 through the hole 26**.
>
> [Campbell at col. 4, lines 26-40; emphasis added in bold.]

Thus, Campbell used horizontal pins, which ran perpendicular to the direction of pull on the bone blocks, to prevent the tapered (cork-shaped) bone blocks from falling out, or being pulled out of their tapered holes.

There is no express suggestion in either Campbell or Beck to take **the longitudinal groove of the Beck, Jr. et al reference** and add it to the side of the tapered xenograft bone-ligament-bone (aka Bone-Tendon-Bone) graft of Campbell. The reason that there is no express suggestion to do so is because any interference screw that pressed against the cork shaped graft of Campbell would have a downward component of force on the opposing wall that would literally pop the cork shaped graft out of the tapered hole. Specifically, Applicants have copied Fig. 2 of Campbell but deleted all of the lines pointing to the number of the various elements. For purposes of this analysis, Fig 2 is analogous to Fig. 4 of Campbell, because the shape of the tapered bone block is the same and there are less interfering lines. In the copied (but enlarged) Fig. 2 shown as **page 8 herein**, the Applicants have added the opposing force vectors (bolded arrows **R** and **X**) to show the directly opposing forces that an interference screw would exert against the bone graft and the wall of the tapered hole in which it was inserted. Any interference screw that was wedged between hole wall **A** and tapered wall **B** of the bone graft would exert equal but opposing forces perpendicular to each of wall **A** and wall **B**. The force **R** against wall B then gets transferred by the bone graft against opposing wall **C**. However, using conventional vector analysis, the force of vector **R** exerted by the tapered bone graft against transferred to opposing hole wall **C** may be resolved into two components shown as **S** and **T**. The line of action of the first component **S** is perpendicular to hole wall C. However, the line of action of the second component **T** presses the tapered bone plug downward along (parallel to) hole wall **C** and out of the hole. Referring to enlarged Fig. 2, the force **R** that is exerted by an interference screw positioned between walls **A** and **B** has a **desired component** of force **S perpendicular** to hole wall **C** that is **equal** to the **undesired component** of force **T** that is pushing the tapered (cork shaped) implant down and out of the hole. In short, the forces exerted by an interference screw on a groove in the

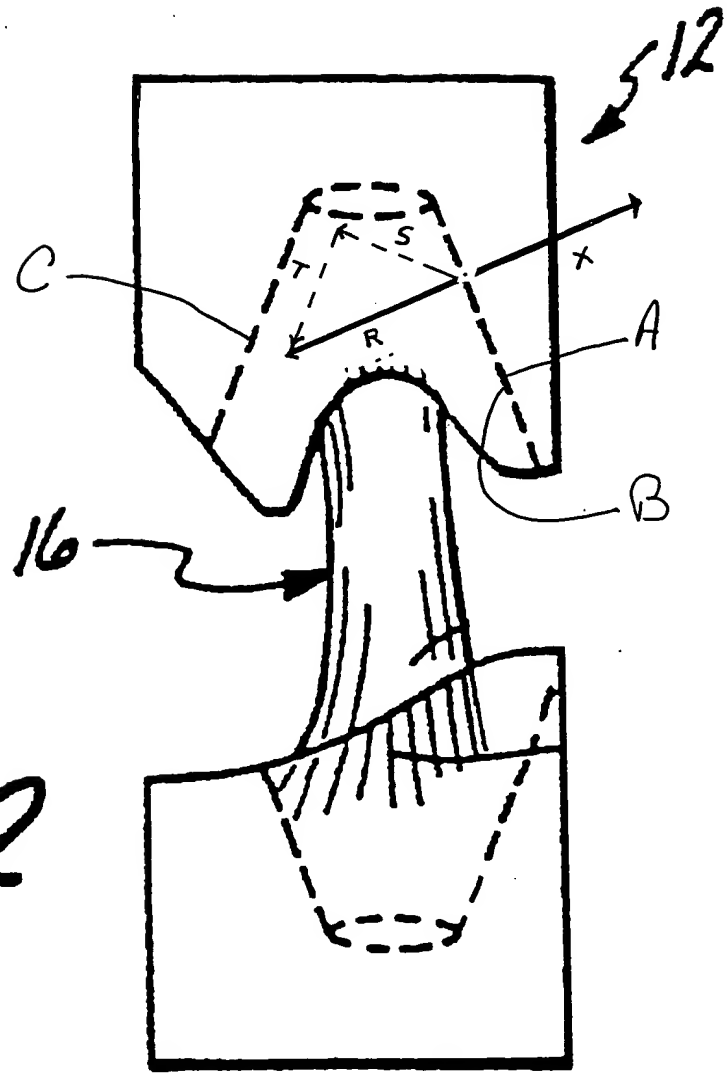
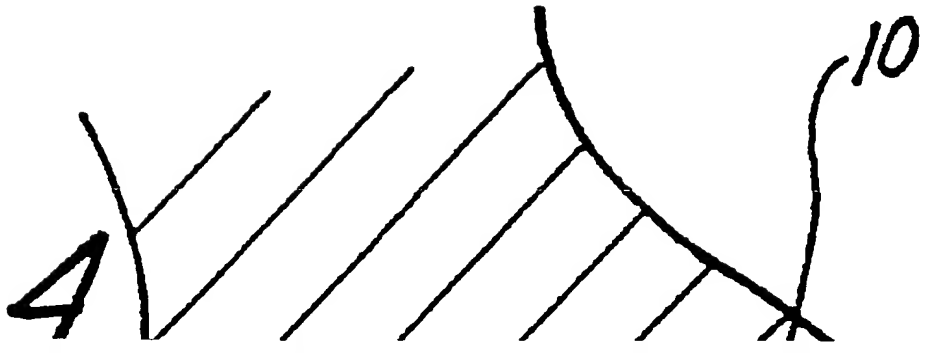


FIG. 2



sidewall of the cork shaped implant of Campbell would literally pop the cork (or cork shaped implant) out of its hole and not provide a graft within the scope of the Applicants' claims, *i.e.*, "a xenograft bone-tendon- bone graft that would be **useful in orthopedic surgery . . . .**" This is one reason why Campbell chose the lateral hole and stainless steel pin combination whereby the tapered graft was retained in its position by lateral pins that resisted all downward pressure, including downward (pulling) pressure during use, until such time as bone remodeling occurred. Any attempt to retain the tapered implant of Campbell with an interference screw would be non-operative for its purpose and would lack utility. For these reasons, the combination of Campbell in view of Beck would not give rise to an operative embodiment of the Applicants' claimed invention.

Separately, the Applicants also wish to point out that the approaches taken by Campbell and Beck, to solving the problem of anterior cruciate ligament repair, are very different. Campbell's approach is to use as natural a B-T-B graft as possible positioned in as natural a position as possible. This means a unitary B-T-B graft having the natural bone to tendon connection at both ends of the tendon. In Campbell's approach, the tapered bone blocks at the ends of the tendons are machined to be received by correspondingly tapered holes in the patient's femur and tibia. Thus, in Campbell's approach, only the bone component of the B-T-B graft ever contacts patient bone. The tendon never touches patient bone.

In contrast, Beck's approach is multi-component with a lot of assembly required. In particular, Beck takes opposing ends of a length of tendon and runs the opposing ends up and down grooves in each of the unitary or assembled anchor bodies. The amount of tendon surface that contacts patient bone is almost as great as the amount of bone anchor surface that contacts patient bone. This means that the assembled B-T-B of Beck relies upon an unnatural connection wherein tendon contacts the inside of the patient bone in a bone tunnel. Moreover, in Beck's approach, the interference screw compresses both soft tendon and the bone anchor against the walls of a bone tunnel so as to retain both in the tunnel.

B. Campbell teaches away from any combination with the bone tunnel approach

Finally, Campbell's approach teaches away from the bone tunnel approach, such as the embodiment disclosed by Beck. Although Campbell issued in 1991, the bone tunnel approach employed by Beck was discussed in Campbell and rejected because of a plurality of problems including the possibility of intraosseous infections and complications:

> Consider, for example, an injured knee joint having a damaged anterior cruciate ligament. Attachment of a replacement ligament according to **existing techniques may involve forming tunnels in the femur and tibia (the host bones)**. The tunnels are formed so that each extends through one of the host bones from an entrance or proximal end of the tunnel at the natural ligament attachment site to an exit or distal end of the tunnel at an outer surface of the host bone.
>
> **Each end of the replacement ligament is passed through one of the tunnels**, from the proximal end to the distal end where it is anchored to the outer surface of the host bone by such means as stapling. This results in **the replacement ligament spanning the intra-articular region between the natural attachment sites somewhat like a natural ligament, but it also results in certain problems that need to be overcome**.
>
> For example, **the replacement ligament extends beyond the natural attachment sites and all the way through the tunnels** to the outer surfaces on the other side of each host bone. This results in the replacement ligament being able to **stretch** over a greater length than a natural ligament (from the outer surface of the femur to the outer surface of the tibia), and this **impairs performance**.
>
> In addition, formations such as bone spicules can form at the entrance to each of the tunnels. These tend to abrade the replacement ligament, cause fatigue of the material, and break off particles which can cause irritation.
>
> Furthermore, the **tunnels provide access to the host bone interior**. As a result, **synovial fluid can migrate from the intra-articular region between host bones into the bone tunnels**. Thus, any activity in the intra-articular region, such as **infection**, can be **easily communicated into the bone interior** and result in **intra-osseous complications**. Similarly, activity within the bone can be easily communicated to the intra-articular region.

> Consequently, it is desirable to have a new and improved replacement ligament and attachment method that overcomes these concerns.
>
> [Campbell at col. 1, lines 18-58; emphasis added in bold.]

Campbell's approach to avoiding synovial fluid migrating into the bone tunnel was to machine a bone plug that exactly fit the hole into which it was inserted. See Fig. 4 of Campbell. To avoid contact with the synovial fluid, the ends of the bone plugs were held in place by stainless steel pins (30 and 32) that were inserted through the sides of the femur and the tibia, well away from the synovial fluid in the joint between the bones. Thus, Campbell **teaches away** from the use of bone grooves and interference screws which would inherently have some space open into the intra-articular region where synovial fluid could migrate and transmit an infection or *vice versa*. *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) ("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**"); emphasis added in bold. For all these reasons, the combination of Campbell in view of Beck would not have made a *prima facie* case of obviousness against the claimed invention. *See In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) ("error to find obviousness where references 'diverge from and teach away from the invention at hand'"); *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983). The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

CONCLUSION

Claims 1-2, 4, 8-9 and 31-40 stand rejected. In view of the arguments and evidence provided herein, all bases for rejecting claims 1-2, 4, 8-9 and 31-40 under 35 U.S.C. §103(a) for alleged obviousness have been rebutted. The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

If the Examiner feels that a telephone call would advance the prosecution of this application, he is invited to telephone the undersigned attorney at the telephone number provided below.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
34th Floor
Chicago, Illinois 60661
(312) 775-8133

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